

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 015/01061	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/IL00/00132	International filing date (day/month/year) 05/03/2000	Priority date (day/month/year) 05/03/1999
International Patent Classification (IPC) or national classification and IPC A61N1/36		
Applicant IMPULSE DYNAMICS (ISRAEL), LTD. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 8 sheets, including this cover sheet.

- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains Indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 05/10/2000	Date of completion of this report 04.05.2001
Name and mailing address of the International preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Schoeffmann, H Telephone No. +49 89 2399 2625 <div style="text-align: right;">  </div>

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IL00/00132

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-33 as originally filed

Claims, No.:

1-35 as originally filed

Drawings, sheets:

1/7-7/7 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

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EXAMINATION REPORT**

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☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 20-35.

because:

☒ the said international application, or the said claims Nos. 32-35 relate to the following subject matter which does not require an international preliminary examination (*specify*):
see separate sheet

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 20-31 are so unclear that no meaningful opinion could be formed (*specify*):
see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos. .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Yes: Claims

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International application No. PCT/IL00/00132

	No:	Claims	1
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1
Industrial applicability (IA)	Yes:	Claims	1
	No:	Claims	

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/IL00/00132

ad III:

1. For the assessment of the present claims 32-35 on the question whether they are industrially applicable, no unified criteria exist in the PCT. The IPEA therefore is not required to carry out an examination on these claims (Cf. Rule 67.1(iv) PCT).

The patentability may be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to methods of treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body.

The above claims pertain to a method of controlling insulin secretion by electro-stimulating the pancreas. Such method might not be regarded as invention susceptible of industrial application.

2. As regards claims 2-31 see item V.4. below.

ad V:

1. Reference is made to the following documents:

D1... WO-A-98/57701

D2... WO-A-99/03533

D3... GB-A-1 394 171

2. Document D1 relates to an apparatus for enhancement of glucose production by stimulation of pancreatic beta cells. The apparatus according to D1 comprises:
 - a glucose sensor, for sensing a level of glucose or insulin in a body serum (cf. page 12, lines 9-10, but also page 13, lines 22-25 and page 10, lines 22-24);
 - at least one electrode, for electrifying an insulin producing cell or group of cells (cf. page 9, lines 12-16);
 - a power source (cf. page 9, line 6: an implantable stimulator necessarily has a power source) for electrifying said at least one electrode with a pulse that does not initiate an action potential in said cell and has an effect of increasing insulin secretion (the amplitude of the D1 stimulator is programmable, so that it is

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/IL00/00132

considered suitable for delivering stimulation pulses that do not initiate action potentials in the pancreatic cells)

- a controller which receives the sensed level and controls said power source to electrify said at least one electrode to have a desired effect on said level (cf. page 9, lines 9-16).

Claim 1 thus lacks novelty in view of D1 so that the requirement of Art.33(2) PCT is not met.

3. D2 discloses, among others, a device for modifying the output of the pancreas by electrical excitation of the glucose producing cells (cf. page 34, lines 4-7). The gist of the invention according to D2 appears to reside in the application of non-excitatory electric fields, ie. fields that do not induce a propagating action potential, in order to modify the production of glucose (cf. D2, page 3, lines 13-22). The D1 apparatus comprises,

- a glucose sensor, for sensing a level of glucose or insulin in a body serum (cf. page 34, lines 22-24);
- at least one electrode, for electrifying an insulin producing cell or group of cells (cf. page 34, lines 14,15);
- a power source (an implantable device needs to have a power source; cf. page 17, lines 18,19) for electrifying said at least one electrode with a pulse that does not initiate an action potential in said cell and has an effect of increasing insulin secretion (cf. page 34, lines 14-17);
- a controller which receives the sensed level and controls said power source to electrify said at least one electrode to have a desired effect on said level (cf. page 34, lines 22-24; claim 113 of D2; page 17, lines 1-19);

Accordingly, the subject-matter of claim 1 also lacks novelty with respect to D2 (Art.33(2) PCT).

4. 20 of the 30 dependent apparatus claims are directly dependent on claim 1. Since each of these claims refers to a separate and distinct embodiment, examination of a manifold of inventions would have been required. Therefore an objection for lack of conciseness under Art.6 PCT is raisable to the file as it stands. The invention to

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EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/IL00/00132

be further prosecuted should have been identified by filing a correspondingly amended claim 1. A new set of claims should have been filed which is concise as required by Art.6 PCT, ie. it should have been limited to a single independent apparatus claim.

At present, the claims indicated below are not considered to define subject-matter that meets the requirement of Art.33(2) PCT in view of D1, D2 and Art.33(3) PCT in view of D3, respectively:

claim 2, see D2, fig.9;
claim 3, see D2, page 17, lines 18,19;
claim 5; see D2, page 8, lines 14-17
claims 6,8,9, see D2, page 8, line 9 to page 9, line 4;
claims 7,11, see D1, page 14, lines 1-28;
claim 10, see D2, the paragraph over pages 16,17
claims 15,16, see D2, the paragraph over pages 11,12;
claims 20,21, cf. first two graphs in fig. 2A of D2;
claims 24-28, see D2, page 13, lines 10-12;
claims 29-31, see D3, page 6, line 72 to page 7, line 13:

ad VII:

1. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
2. Independent claim 1 is not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (at present, document D2 appears most pertinent; cf. item V.3. above) being placed in a preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in a characterising part (Rule 6.3(b)(ii) PCT).
3. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in documents D1 to D3 is not mentioned in the description, nor are

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International application No. PCT/IL00/00132

these documents identified therein.

ad VIII:

1. The passage "incorporated by references" as at pages 1,11 and 18 may be allowable only if the requirements as set out in the Guidelines for the preliminary examination C-II.4.17 and 4.17a are met. Deletion of these passages appeared necessary.
2. Many of the dependent claims are drafted by either mere indication of their intended use (cf. claims 2,4), or in terms of the result to be achieved which merely amounts to a statement of the underlying problem (cf. claims 6,7,8,9,11,13,26,27,28). The intended limitations are therefore not clear from these claims, contrary to the requirements of Article 6 PCT. The technical features necessary for achieving the desired results and the features which make the device suitable for their intended use thus should have been added.

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From the INTERNATIONAL BUREAU

NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

No.
FENSTER, Paul
Fenster & Company Patent
Attorneys Ltd.
P.O. Box 10256
49002 Petach Tikva
ISRAEL

Date of mailing (day/month/year) 14 September 2000 (14.09.00)		
Applicant's or agent's file reference 015/01061		IMPORTANT NOTICE
International application No. PCT/IL00/00132	International filing date (day/month/year) 05 March 2000 (05.03.00)	Priority date (day/month/year) 05 March 1999 (05.03.99)
Applicant IMPULSE DYNAMICS (ISRAEL) LTD. et al		

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:

AU, KP, KR, US



In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:

AE, AL, AM, AP, AT, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EA, EE, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, OA, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW

The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).

3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on 14 September 2000 (14.09.00) under No. WO 00/53257.

REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, a demand for international preliminary examination must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))

If the applicant wishes to proceed with the international application in the national phase, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer J. Zahra
Facsimile No. (41-22) 740.14.35	Telephone No. (41-22) 338.83.38

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 015/01061	FOR FURTHER ACTION		see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
International application No. PCT/IL 00/ 00132	International filing date (day/month/year) 05/03/2000	(Earliest) Priority Date (day/month/year) 05/03/1999	
Applicant IMPULSE DYNAMICS (ISRAEL), LTD. et al.			

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 6 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☒ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☐ the text is approved as submitted by the applicant.

☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is Figure No.

☒ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

1 _____
☐ None of the figures.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL 00/00132

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 32-35
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

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Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

The abstract is changed as follows:

Line 1: after "controller" insert "(102)";
line 2: after "sensor" insert "(118)";
line 3: after "electrode" insert "(110,112)";
line 4: after "source" insert "(104)";
line 6: after "controller" insert "(106)".

INTERNATIONAL SEARCH REPORT

International Application No

PCT/IL 00/00132

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61N1/36

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61N A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, INSPEC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99 03533 A (FENSTER MAIER; BEN HAIM SHLOMO (IL); DARVISH NISSIM (IL); FELZEN B) 28 January 1999 (1999-01-28) cited in the application page 34, line 4 - line 24	1-28
X	WO 98 57701 A (MEDTRONIC INC) 23 December 1998 (1998-12-23) cited in the application page 9, line 5 -page 10, line 29	1-28
X	WO 93 02743 A (CYBERONICS INC) 18 February 1993 (1993-02-18) page 11, line 24 - line 18 page 13, line 18 - line 26 page 18, line 11 -page 19, line 23 -/-	1-4,6-28

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

21 June 2000

Date of mailing of the international search report

28/06/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Knüpling, M

INTERNATIONAL SEARCH REPORT

International Application No

PCT/IL 00/00132

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>GB 1 394 171 A (WHITTAKER CORP) 14 May 1975 (1975-05-14) page 6, line 109 - line 124 page 5, line 85 - line 90</p>	1,3,29

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IL 00/00132

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9903533	A	28-01-1999	AU 3458197 A EP 0996482 A	10-02-1999 03-05-2000
WO 9857701	A	23-12-1998	US 5919216 A EP 0989884 A	06-07-1999 05-04-2000
WO 9302743	A	18-02-1993	US 5231988 A AU 2428292 A JP 7503865 T	03-08-1993 02-03-1993 27-04-1995
GB 1394171	A	14-05-1975	NONE	

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

RECEIVED

- 9 - 05 - 2001

PCT FENSTER & Co.

To:

FENSTER, Paul et al.
FENSTER & COMPANY
PATENT ATTORNEYS, LTD.
P.O. Box 10256
Petach Tikva 49002
ISRAEL

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT (PCT Rule 71.1)

Date of mailing
(day/month/year) 04.05.2001

Applicant's or agent's file reference
015/01061

IMPORTANT NOTIFICATION

International application No.
PCT/IL00/00132

International filing date (day/month/year)
05/03/2000

Priority date (day/month/year)
05/03/1999

Applicant
IMPULSE DYNAMICS (ISRAEL), LTD. et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized officer

Marra, E

Tel. +49 89 2399-7235



091914889

Copy for the Elected Office (EO/US)

PATENT COOPERATION TREATY

PCT/IL00/00132

3762

PCT

From the INTERNATIONAL BUREAU

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

To:

FENSTER, Paul
Fenster & Company Patent
Attorneys, Ltd.
P.O. Box 10256
49002 Petach Tikva
ISRAËL

Date of mailing (day/month/year)

19 September 2001 (19.09.01)

Applicant's or agent's file reference

015/01061

International application No.

PCT/IL00/00132

IMPORTANT NOTIFICATION

International filing date (day/month/year)

05 March 2000 (05.03.00)

1. The following indications appeared on record concerning:



the applicant



the inventor



the agent



the common representative

Name and Address

IMPULSE DYNAMICS (ISRAEL), LTD.
P.O. Box 2044
39120 Tirat Hacarmel
Israel

State of Nationality

IL

State of Residence

IL

Telephone No.

+972 (4) 857-6756

Facsimile No.

+972 (4) 857-6753

Teleprinter No.

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:



the person



the name



the address



the nationality



the residence

Name and Address

IMPULSE DYNAMICS NV
3 L.B. Smithplein
Curacao
Netherlands Antilles

State of Nationality

NL

State of Residence

NL

Telephone No.

Facsimile No.

Teleprinter No.

3. Further observations, if necessary:

4. A copy of this notification has been sent to:



the receiving Office



the International Searching Authority



the International Preliminary Examining Authority



the designated Offices concerned



the elected Offices concerned



other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

François BAECHLER

Telephone No.: (41-22) 338.83.38

Copy for the Elected Office (EO/US)
PATENT COOPERATION TREATY

PCT/IL00/00132

PCT

NOTIFICATION OF THE RECORDING
OF A CHANGE

(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

FENSTER, Paul
Fenster & Company Patent
Attorneys, Ltd.
P.O. Box 10256
49002 Petach Tikva
ISRAËL

Date of mailing (day/month/year)

19 September 2001 (19.09.01)

Applicant's or agent's file reference

015/01061

International application No.

PCT/IL00/00132

IMPORTANT NOTIFICATION

International filing date (day/month/year)

05 March 2000 (05.03.00)

1. The following indications appeared on record concerning:

☒

the applicant

☒

the inventor

☐

the agent

☐

the common representative

Name and Address

DARWISH, Nissim
Hantke Street 22A
34606 Haifa
Israel

State of Nationality

IL

State of Residence

IL

Telephone No.

Facsimile No.

Teleprinter No.

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☐

the person

☒

the name

☐

the address

☐

the nationality

☐

the residence

Name and Address

DARVISH, Nissim
Hantke Street 22A
34606 Haifa
Israel

State of Nationality

IL

State of Residence

IL

Telephone No.

Facsimile No.

Teleprinter No.

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

☒

the receiving Office

☐

the International Searching Authority

☐

the International Preliminary Examining Authority

☐

the designated Offices concerned

☒

the elected Offices concerned

☐

other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

François BAECHLER

Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room 524
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE
ETATS-UNIS D'AMERIQUE
in its capacity as elected Office

Date of mailing (day/month/year)

26 October 2000 (26.10.00)

International application No.

PCT/IL00/00132

Applicant's or agent's file reference

015/01061

International filing date (day/month/year)

05 March 2000 (05.03.00)

Priority date (day/month/year)

05 March 1999 (05.03.99)

Applicant

DARWISH, Nissim et al

1. The designated Office is hereby notified of its election made:



in the demand filed with the International Preliminary Examining Authority on:

05 October 2000 (05.10.00)



in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was

was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

R. E. Stoffel

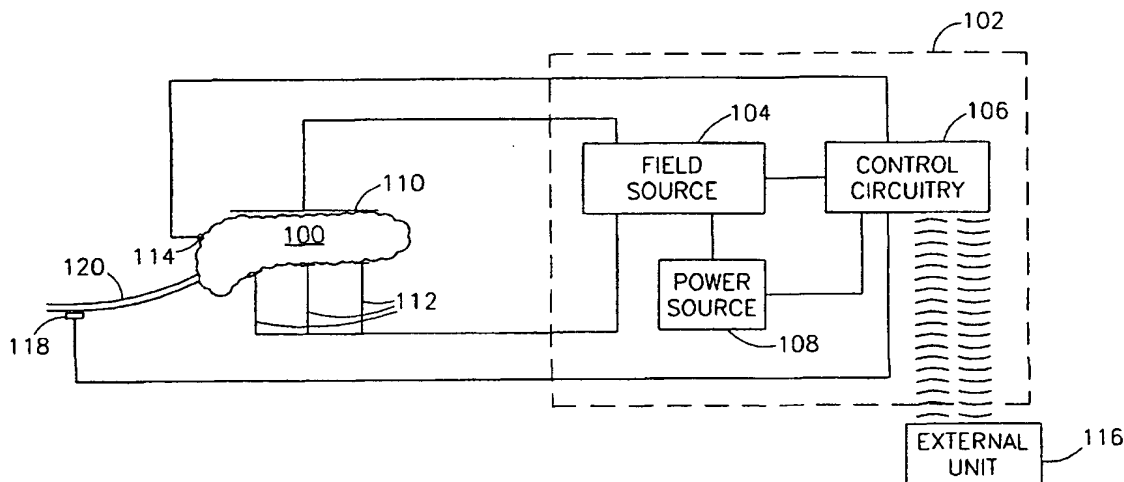
Telephone No.: (41-22) 338.83.38



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁷ : A61N 1/36		A1	(11) International Publication Number: WO 00/53257
			(43) International Publication Date: 14 September 2000 (14.09.00)
(21) International Application Number: PCT/IL00/00132 (22) International Filing Date: 5 March 2000 (05.03.00) (30) Priority Data: 60/123,532 5 March 1999 (05.03.99) US (63) Related by Continuation (CON) or Continuation-in-Part (CIP) to Earlier Application US 60/123,532 (CON) Filed on 5 March 1999 (05.03.99) (71) Applicant (for all designated States except US): IMPULSE DYNAMICS (ISRAEL), LTD. [IL/IL]; P.O. Box 2044, 39120 Tirat Hacarmel (IL). (72) Inventors; and (75) Inventors/Applicants (for US only): DARWISH, Nissim [IL/IL]; Hantke Street 22A, 34606 Haifa (IL). HAREL, Tami [IL/IL]; Harel Street 22, 34555 Haifa (IL). FELSEN, Bella [IL/IL]; Hatzvi Street 26, 34355 Haifa (IL). (74) Agents: FENSTER, Paul et al.; Fenster & Company Patent Attorneys, Ltd., P.O. Box 10256, 49002 Petach Tikva (IL).		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>	

(54) Title: BLOOD GLUCOSE LEVEL CONTROL



(57) Abstract

A pancreatic controller (102), comprising: a glucose sensor (118), for sensing a level of glucose or insulin in a body serum; at least one electrode (110, 112), for electrifying an insulin producing cell or group of cells; a power source (104) for electrifying said electrode with a pulse that does not initiate an action potential in said cell and has an effect of increasing insulin secretion; and a controller (106) which receives the sensed level and controls said power source to electrify said electrode to have a desired effect on said level.

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
International application No. PCT/IL03/00736	International filing date (day/month/year) 04 September 2003 (04.09.2003)	(Earliest) Priority Date (day/month/year) 05 September 2002 (05.09.2002)
Applicant IMPLUSE DYNAMICS NV		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.



It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the Report

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

2. ☐ Certain claims were found unsearchable (See Box I).

3. ☐ Unity of invention is lacking (See Box II).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☐ the text is approved as submitted by the applicant.

☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 1

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☒ because this figure better characterizes the invention.

☐ None of the figures

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IL03/00736

Box III TEXT OF THE ABSTRACT (Continuation of Item 5 of the first sheet)

A method of glucose level control, comprising providing at least one electrode (110, 112) adapted to apply an electric field to a pancreas (100); and applying an electric field to the pancreas using said at least one electrode such that blood glucose levels are significantly reduced and blood insulin levels are not significantly increased.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IL03/00736

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61N 1/18
US CL : 607/40

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 607/40

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,031,617 A (KLETTNER) 16 July 1991, see abstract.	1

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

"A"	document defining the general state of the art which is not considered to be of particular relevance	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E"	earlier application or patent published on or after the international filing date	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O"	document referring to an oral disclosure, use, exhibition or other means	"&"	document member of the same patent family
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

05 February 2004 (05.02.2004)

Date of mailing of the international search report

13 SEP 2004

Name and mailing address of the ISA/US

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Commissioner for Patents
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